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Safety and Functionality of a Guidewire Fixator: Clinical Investigation of a New Endovascular Tool

Liungman, Krister ; Mani, Kevin ; Wanhainen, Anders ; Bosaeus, Linus ; Lachat, Mario

Abstract: **OBJECTIVE** A new endovascular tool, the Liungman Guidewire Fixator, has been developed to simplify endovascular treatment in complex aortic aneurysms. The device has been extensively tested in bench models and animal trials. To verify the safety and functionality demonstrated in the porcine model, the device was tested in ten patients undergoing endovascular aortic repair (EVAR) or fenestrated endovascular aortic repair (f-EVAR) treatment for abdominal aortic aneurysm. **METHODS** The Liungman Guidewire Fixator consists of a braided stent-like, cylindrical structure with conical ends and a central channel for a 0.035 guidewire. When in use, it is slid along the guidewire and positioned in the target artery, where the Liungman Guidewire Fixator interacts with the arterial wall by anchoring the guidewire to the wall through a radial force. The Liungman Guidewire Fixator allows for uninterrupted blood flow passed the point of fixation. In this study, the Liungman Guidewire Fixator was tested in ten patients undergoing EVAR or f-EVAR treatment for abdominal aortic aneurysm. The device was deployed and retrieved crossover into the hypogastric artery, and the occurrence of thrombotic occlusion, arterial dissection, and vascular rupture or trauma was studied using angiography, as well as device ability to withstand guidewire tension. **RESULTS** There were no instances of occlusion, dissection, or vascular trauma detected using angiography. In all cases, deployment and retrieval were successful, and the devices could withstand an applied tension of 3 N. In one instance, retrieval was challenging because of significant tortuosity, which was resolved by a coaxial catheterization. **CONCLUSIONS** Deployment was uneventful in all ten patients. Retrieval according to the intended instruction for use was performed in nine of the patients. In one patient, a coaxial catheterization was necessary. All devices withstood a retention force of 3 N.

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OPEN

Safety and Functionality of a Guidewire Fixator

Clinical Investigation of a New Endovascular Tool

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Objective: A new endovascular tool, the Liungman Guidewire Fixator, has been developed to simplify endovascular treatment in complex aortic aneurysms. The device has been extensively tested in bench models and animal trials. To verify the safety and functionality demonstrated in the porcine model, the device was tested in ten patients undergoing endovascular aortic repair (EVAR) or fenestrated endovascular aortic repair (f-EVAR) treatment for abdominal aortic aneurysm.

Methods: The Liungman Guidewire Fixator consists of a braided stent-like, cylindrical structure with conical ends and a central channel for a 0.035" guidewire. When in use, it is slid along the guidewire and positioned in the target artery, where the Liungman Guidewire Fixator interacts with the arterial wall by anchoring the guidewire to the wall through a radial force. The Liungman Guidewire Fixator allows for uninterrupted blood flow passed the point of fixation. In this study, the Liungman Guidewire Fixator was tested in ten patients undergoing EVAR or f-EVAR treatment for abdominal aortic aneurysm. The device was deployed and retrieved crossover into the hypogastric artery, and the occurrence of thrombotic occlusion, arterial dissection, and vascular rupture or

trauma was studied using angiography, as well as device ability to withstand guidewire tension.

Results: There were no instances of occlusion, dissection, or vascular trauma detected using angiography. In all cases, deployment and retrieval were successful, and the devices could withstand an applied tension of 3 N. In one instance, retrieval was challenging because of significant tortuosity, which was resolved by a coaxial catheterization.

Conclusions: Deployment was uneventful in all ten patients. Retrieval according to the intended instruction for use was performed in nine of the patients. In one patient, a coaxial catheterization was necessary. All devices withstood a retention force of 3 N.

Key Words: Guidewire fixator, Guidewire tension, Aortic aneurysm, Stent graft, Fenestration.

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Endovascular treatments of aneurysm and occlusive arterial diseases are rapidly expanding and successively replacing open surgery procedures.¹ During complicated reconstructive aortic procedures such as f-EVAR, positioning of the fenestrated stent graft and catheterization of the visceral arteries are often difficult because of tortuous vascular anatomy, angulation, irregular vascular lumen, and variable distorted takeoff of the visceral arteries.² It may also be difficult to acquire and maintain a stable guidewire position in the target artery for positioning of the bridging stent graft. Today, this can be achieved by inflating a balloon parallel to the guidewire, thereby trapping the wire and thus obtaining distal stability. A new endovascular tool was developed to simplify complex aortic endovascular procedures by allowing anchoring of the guidewire in the target artery, before positioning of the stent graft, and to simplify insertion of the sheath in the target artery to position the bridging stent graft, see Video (Supplemental Digital Content 1, <http://links.lww.com/INNOV/A167>). The safety and functionality of the device have been previously tested in a porcine animal model.³ A simplistic case of a single fenestration f-EVAR in a pig model under anesthesia has been previously published.⁴

Guidewire stability is also valuable in other endovascular procedures because distal fixation enables tension on the guidewire and thereby better procedure guidance, e.g., for crossover treatment of peripheral arterial disease.

The present study was conducted to verify the animal testing under clinical conditions in man.

METHODS

Ten patients with abdominal pararenal or thoracoabdominal aortic aneurysms were recruited for a test performed in conjunction



Video clip is available online.

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Disclosures: Krister Liungman, MD, PhD, is the founder of Endovascular Development Ltd, Uppsala, Sweden, that owns the intellectual rights to the Liungman Guidewire Fixator. Linus Bosaeus, MS, is employed by Endovascular Development Ltd. Mario Lachat, MD, PhD, works as a consultant for Endospan, Herzlia, Israel, and JOTEC, Hechingen, Germany. Kevin Mani, MD, PhD, and Anders Wanhainen, MD, declare no conflicts of interest.

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with a planned endovascular stent graft treatment. The procedure was performed before treatment. The clinical investigation involved a computed tomography follow-up after procedure in accordance with the standard protocol for the stent graft treatment.

Approval for the study was obtained from the research ethics committee of Uppsala and the Medical Product Agency Sweden. All patients enrolled received oral and written information of the research project and the procedure. Signed informed consent was received before the clinical test and treatment.

The Liungman Guidewire Fixator (LGF) device consists of a nitinol braided, stent-like, expandable cylinder with conical ends, of a pre-set size, with a central lumen for a 0.035" guidewire. The LGF runs freely over a guidewire up to a stopper mounted close to the distal end. Upon traction of the guidewire, distal interaction of the stopper causes longitudinal compression of the LGF, which translates into radial expansion that anchors the LGF and guidewire. The fixator is part of an integrated system that entails the guidewire and a retrieval catheter with a screw mechanism for catch and release of the device (Fig. 1). The LGF is delivered through a conventional 7F introducer sheath, e.g., Terumo Destination (Terumo Medical Corporation, Elkton, MD USA) or COOK Ansel Check Flo (Cook Incorporated, Bloomington, IN USA). A transparent intubation tube helps pass the LGF through the valve of the introducer sheath. A torque device is provided to aid turning the retrieval catheter, for release and catch of the threaded catching mechanism of the LGF.

A conventional 12F COOK sheath (Cook Incorporated, Bloomington, IN USA) was used for crossover access and a conventional Terumo guidewire and angio catheter (Terumo Medical Corporation, Elkton, MD USA) for catheterization of the contralateral hypogastric artery. A force gauge (HF 50, M&A Instruments Incorporated, Los Angeles, CA USA) was used for measurement of a 3-N retention force applied to the anchored guidewire.

The arterial system was cannulated in a conventional manner and a 30-cm 12F Cook introducer (Cook Incorporated, Bloomington, IN USA) was inserted. This introducer was brought to a crossover position just above the hypogastric artery takeoff on the contralateral side. The contralateral hypogastric artery was catheterized with a 7F Terumo Destination introducer (Terumo Medical Corporation, Elkton, MD USA). The LGF guidewire was positioned in the target artery, and the LGF was

introduced over the LGF guidewire and deployed in the first segment of the contralateral hypogastric artery (Fig. 2). In agreement with instruction for use, the LGF size should be at least 1 mm larger than the target artery. The size of the LGFs used in this study was chosen to be either 8 or 11 mm to accord with the dimensions of the targeted hypogastric arteries. The force gauge was used to measure a predetermined force of 3 N. After completed measurement, the LGF was recaptured and retrieved by the retrieval catheter. The intended EVAR/f-EVAR procedure was then performed in a conventional manner.

RESULTS

All deposits were completed uneventfully. Nine retrievals were completed without difficulty. In one case, because of difficulty to turn the retrieval catheter in the 7F sheath to catch the LGF screw fitting, an alternative method for retrieval was used. The cause for this problem was multiple perpendicular bends of tortuous iliac arteries, causing increased friction in the 7F introducer. By using a coaxial access with a 7F introducer in a 12F introducer, the problem was overcome. In all instances, the force of 3 N was applied without dislocation of the LGF. During the procedure and at completion, an angiography showed undisturbed blood flow with no sign of dissection or arterial trauma (Fig. 2).

DISCUSSION

The aim of this study was to clinically verify the findings from the preclinical safety and functionality study, performed in a porcine model. Deposition and retrieval of the LGF were uneventful in the preclinical study. No arterial thrombotic occlusion, dissection, or trauma occurred. The mean force necessary to dislocate the LGF was 7.6 N with a range from 2.8 to 17.4 N.³

The present clinical study showed similar results, except for one episode of capture and retrieval of the LGF that, because of multiple bends in a very tortuous iliac anatomy, necessitated a coaxial catheter approach for retrieval. This experience motivated a change of recommendation in the instruction for use. Our conclusion was to use coaxial access in all depositions and retrievals of the LGF. This strategy agrees with the technique used in other procedures with multiple bends and kinks of the arterial anatomy, where a stent or stentgraft is introduced through an introducer.

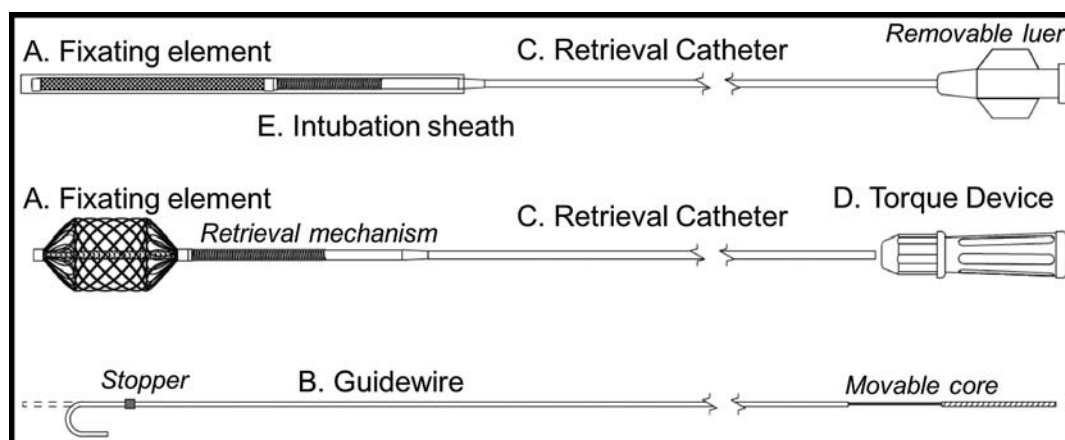


FIGURE 1. The Liungman Guidewire system overview. Reprinted with permission from Bosaeus et al. *Innovations*. 2017;12:265–268.

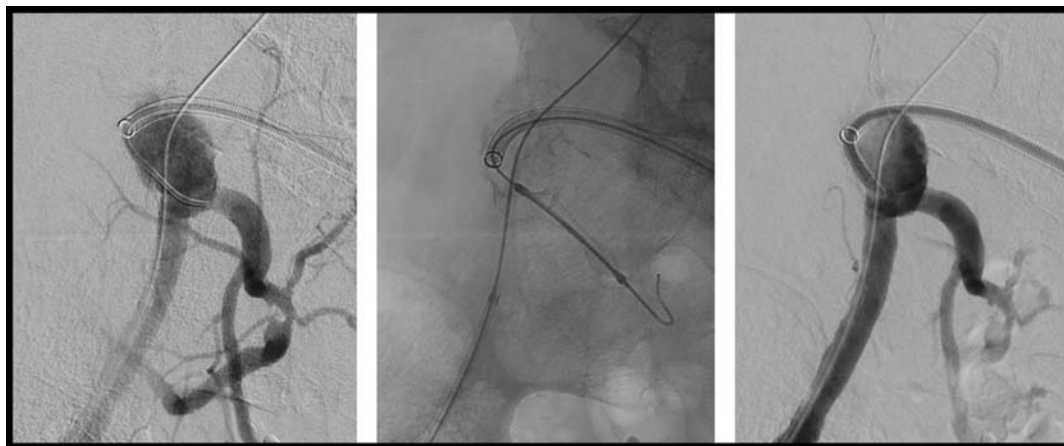


FIGURE 2. Left, Angiogram of left hypogastric artery before LGF deployment. Center, LGF, positioned in the left hypogastric artery (fluoroscopy). Right, Angiogram of left hypogastric artery after LGF retrieval.

Distal guidewire fixation is a new concept that enables new guidewire techniques. Wire stability enhances the surgeon's ability to work in parallel and reduces the risks for loss of wire position. The distal fixation also allows wire tension, which can add to wire stiffness during insertion of a large sheath or other medical devices, e.g., introducing a sheath to position the bridging stent graft through the fenestration into the target artery. Furthermore, distal fixation allows repositioning of the proximal end of the guidewire, which can be used, e.g., during fenestrated and branched aortic repair to access angled target artery takeoff.⁴

The force of fixation tested in this study was 3 N. This force was chosen as the necessary retaining force needed to hold the guidewire during an endovascular procedure was anticipated to be limited and of this magnitude.

In view of verification of the findings during preclinical testing in a porcine model, and the uneventful course of this clinical trial, the LGF was considered to be safe and functional during

tested conditions in the hypogastric artery. To further investigate proper use and clinical risks, the device will be subjected to a postmarket clinical follow-up study to capture any treatment or procedure specific risks not covered in this study.

The LGF is presently Conformité Européenne approved but not Food and Drug Administration cleared and is not available for sale.

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